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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,200	10/08/2004	Charles Edward Owen	DC/4-32002A	9196

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,200	OWEN ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 36* is/are pending in the application.

4a) Of the above claim(s) *5 and 14-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-13 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/08/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This application is a national stage entry under 35 USC 371 of PCT/EP03/00154 which was filed 01/09/2003, and which claims foreign priority to the British document 0200429.9 filed 01/09/2002.

Applicant's response and amendment received October 14, 2005 is acknowledged.
Claims 26-35 have been canceled.
Claims 1-25 and 36 are pending in the instant application.

Applicant's election with traverse of Group I, claims 1-13 and 36, drawn to pharmaceutical compositions comprising anti-IgE antibodies and an antiallergic compound, and the species election of pimecrolimus (33-epichloro, 33-desoxyascomycin) as an antiallergic compound in the reply filed on October 14, 2005 is acknowledged. The traversal is on the grounds that there is no burden to search all the groups and species simultaneously. This is not found persuasive because search burden is not a criteria used in establishing that an invention lacks Unity of Invention in an application filed under 35 USC 371.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5, and 14-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species. Applicant timely traversed the restriction (election) requirement in the reply filed on October 14, 2005.

Note that claims 14-25 are drawn to methods, and that the additional antiallergic compound recited in claim 5 is a monoclonal antibody, a species that is distinct from the elected species of pimecrolimus. Note also that applicant's reply to the restriction requirement is not fully responsive in that it does not list the claims that read upon the elected species, a requirement communicated to applicant in paragraph 3 of section 5 on page 3 of the restriction requirement mailed September 20, 2005.

Specification

2. Applicant is requested to amend the first line of the specification to indicate that the instant application is the national stage entry under 35 USC 371 of PCT/EP03/00154 which was filed 01/09/2003, and which claims foreign priority to the British document 0200429.9 filed 01/09/2002.

The use of many trademarks has been noted in this application. Trademarked products should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

3. Claim 10 is objected to because the term "epichloro" is misspelled in line 2 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4, 6-13, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are drawn to a composition that appears to comprise an anti-IgE antibody and another antiallergic compound. Thus it appears that the composition of claim 1 and its dependent claims minimally contains two active ingredients that are admixed. This interpretation of the claim is supported by the definition of composition in Webster's New World Dictionary wherein a composition is defined as "a mixture of several parts or ingredients" (see provided copy of the definition included with this office action). However, lines 6 and 7 of claim 1 indicate that the composition can be used simultaneously, separately, or sequentially. While it is possible to administer two active ingredients that are mixed together (i.e. the anti-IgE antibody and the other antiallergic compound) simultaneously, it is not clear how these mixed ingredients can then be administered separately or sequentially. It would appear that if the active ingredients are to be administered

separately or sequentially, they cannot be mixed together before their use, and thus they would not be a composition such as the one recited in lines 1-5 of claim 1. Appropriate clarification of the structure and constituent components that comprise the instant claimed composition is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuberbier et al. (J. Allergy Clin. Immunol. 2001, 108:275-280, see entire document).

Zuberbier et al. teach compositions of anti-IgE antibodies and pimecrolimus that are administered to tissue culture cells (see entire document, particularly the abstract and Materials and Methods subsection). The anti-IgE antibody and pimecrolimus were not administered simultaneously, but were administered separately and sequentially since pimecrolimus was added to cells five minutes prior to the administration of anti-IgE antibodies (see particularly Figures 1-4 and 6, and the first two paragraphs of the Results subsection). Given the uncertainty concerning the structure and ingredients present in the composition that is recited in the instant claims as discussed above, it

appears reasonable that the sequential administration of pimecrolimus and anti-IgE antibodies meets the recited requirements for a composition of the instant claims.

Therefore, the prior art anticipates the claimed invention.

8. Claims 1-4, 6-9, 12, 13, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowman et al. (US Patent 5,994,511, of record, see entire document) as evidenced by the instant specification.

Lowman et al. teach the monoclonal anti-IgE antibody e25 and its use in treating allergic diseases such as asthma (see entire document, particularly from line 5 of column 1 to line 2 of column 3, and lines 52-67 of column 14). Omalizumab is the generic name for the antibody e25 (see particularly lines 1-5 of page 4 of the instant specification). Lowman et al. disclose that e25 can be present in pharmaceutical compositions comprising more than one active ingredient, with particularly desirable ingredients being immunosuppressive agents (see particularly from line 54 of column 52 to line 25 of column 55, most particularly lines 17-24 of column 54). Specific immunosuppressive agents taught by Lowman et al. include cyclosporine A, FK506, and rapamycin (see particularly from line 59 of column 12 to line 30 of column 13, most particularly lines 15 and 27 of column 13). Lowman et al. also teach their invention in a kit form (see particularly lines 30-47 of column 57).

Therefore, the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowman et al. (US Patent 5,994,511, of record, see entire document) as evidenced by the instant specification, in view of Zuberbier et al. (J. Allergy Clin. Immunol. 2001, 108:275-280, see entire document).

The teachings of Lowman have been discussed above. These teachings differ from the instant claimed invention in that while Lowman et al. do teach pharmaceutical compositions comprising Omalizumab and the immunosuppressants cyclosporine A, FK506, and rapamycin, they do not teach Omalizumab in combination with the specific macrolide T cell immunosuppressant pimecrolimus.

Zuberbier et al. compared the effectiveness of pimecrolimus to commonly used immunosuppressants such as cyclosporine A, FK506, and rapamycin in a number of experimental settings, and teach that pimecrolimus offers an advantage over these

currently used immunosuppressant drugs in that pimecrolimus is a highly specific antagonist of mast cell mediator release that has a low adverse side effect profile (see entire document, particularly the abstract, Figures 1-6, and the Discussion section starting on page 277, most particularly the last paragraph of page 280).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute pimecrolimus for the immunosuppressant used in the compositions taught by Lowman et al. in order to gain the advantage of using a highly specific antagonist of mast cell mediator release that has a low adverse side effect profile as taught by Zuberbier et al.

11. No claims are allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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December 16, 2005

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